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## Quality of life of older rectal cancer patients is not impaired by a permanent stoma

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### Abstract

**Background:** The current study was undertaken to investigate the impact of a stoma on the HRQL with a special focus on age.

**Materials and methods:** Using the Eindhoven Cancer Registry, rectal cancer patients diagnosed between 1998 and 2007 in 4 hospitals were identified. All patients underwent TME surgery. Survivors were approached to complete the SF-36 and EORTC QLQ-C38 questionnaires. HRQL scores of the four groups, stratified by stoma status (stoma/no stoma) and age at operation (<70 and ≥70), were compared. The SF-36 and the QLQ-CR38 sexuality subscale scores of the survivors were compared with an age- and sex-matched Dutch norm population. **Results:** Median follow-up of 143 patients was 3.4 years. Elderly had significantly worse physical function ( $p = 0.0003$ ) compared to younger patients. Elderly ( $p = 0.005$ ) and patients without a stoma ( $p = 0.009$ ) had worse sexual functioning compared to younger patients and patients with a stoma. Older males showed more sexual dysfunction ( $p = 0.01$ ) when compared to younger males. In comparison with the normative population, elderly with a stoma had worse physical function ( $p < 0.01$ ), but slightly better mental health ( $p < 0.05$ ). Elderly without a stoma had better emotional role function ( $p < 0.01$ ), and younger patients had worse sexual functioning and enjoyment (both  $p < 0.0001$ ).

**Conclusions:** Older patients with a stoma have comparable HRQL to older patients without a stoma or the normative population, indicating the feasibility of a permanent stoma for elderly patients with a low situated rectal carcinoma. The negative impact of treatment on sexual functioning as found in the current study calls for further attention to alleviate this problem in sexually active patients.

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**Keywords:** Quality of life; Stoma; Elderly; Colo-anal anastomosis; Sexual function

### Introduction

In rectal cancer surgery patients typically undergo a sphincter preserving procedure (low anterior resection: LAR) or abdominoperineal resection (APR) resulting in a permanent colostomy. The choice for one of these procedures depends on the level of the tumor, the technical feasibility to perform an anastomosis and the condition of the patient. Usually a LAR is preferred when a 1–2 cm tumor-free distal resection margin is feasible.<sup>1,2</sup> However, the number of postoperative problems after LAR is high, especially after neo-adjuvant radiochemotherapy with

anastomotic leakage being the most feared complication due to its potentially devastating consequences.<sup>3</sup> Besides these traditional clinical arguments, health-related quality of life (HRQL) is increasingly accepted as an indicator for treatment efficacy.<sup>4,5</sup> Intuitively, it is conceivable that avoiding a permanent stoma will result in a better HRQL. However, this was challenged by two recent reviews investigating the influence of a stoma on the HRQL showing no relevant impact of a permanent stoma.<sup>4,5</sup>

Balancing the assumed benefits of a colo-anal anastomosis against the potential postoperative complications may be especially difficult in the elderly and frail patients. Patients with comorbidity and less physiologic reserves may not be capable to cope with complications. An alternative for these patients could be a Hartmann's procedure with

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resection of the tumor but without restoration of bowel continuity.

Knowledge of the impact of a stoma on the HRQL may help to determine a treatment strategy for elderly patients suffering from rectal cancer that is both safe and preserves a good HRQL. Unfortunately, studies investigating the impact of treatment on the HRQL in elderly rectal cancer patients are scarce.<sup>6,7</sup> The current study was undertaken to investigate the impact of a stoma on the HRQL with a special focus on age.

## Methods

### *Setting and participants*

This study is part of a (long-term) cancer survivorship study of rectal cancer patients registered at the Eindhoven Cancer Registry (ECR) which collects data on all newly diagnosed cancer patients in the southern part of the Netherlands.<sup>8</sup> Patients diagnosed with rectal cancer in the period 1998–2007 were eligible. Details of the selection process have been reported elsewhere.<sup>9</sup> The survivorship study was designed to evaluate various patient-reported outcomes such as late/long-term effects, and physical and mental health status. Patient-reported outcome data was collected via the PROFILES (Patient Reported Outcomes Following Initial treatment and Long term Evaluation of Survivorship) registry.<sup>10</sup> Data from the PROFILES registry will be available for non-commercial scientific research, subject to study question, privacy and confidentiality restrictions, and registration ([www.profilesregistry.nl](http://www.profilesregistry.nl)).

For the current study, all rectal cancer patients (tumor  $\leq 10$  cm anal verge) with a completed questionnaire from 4 hospitals were selected; Catharina Hospital (Eindhoven), Elkerliek Hospital (Helmond-Deurne), Maxima Medical Center (Eindhoven-Veldhoven) and St. Anna Hospital (Geldrop), all situated in the southeast of the Netherlands. Of the 156 eligible patients, only those who underwent TME-surgery (APR or LAR) were selected. Thirteen patients were excluded for the following reasons: transanal endoscopic microsurgery ( $n = 5$ ), distant metastasis at time of surgery ( $n = 1$ ), received radiotherapy only ( $n = 1$ ), lost to follow-up ( $n = 6$ ) resulting in 143 patients.

### *Data collection*

Eligible survivors received a letter from their treating physician explaining the purpose of the study. The letter explained that by completing and returning the enclosed questionnaire survivors consented to participate in the study and agreed to the linkage of the questionnaire data with their disease history in the ECR. Survivors were reassured that non-participation had no consequences on their follow-up care or treatment. Non-respondents were sent a reminder letter and a questionnaire after 2 months.

For this study, routinely collected data on tumor and patient characteristics by the ECR was augmented by extra

clinical data extracted by one of the authors (RGO) from the patients' medical records. Extra clinical parameters extracted included distance of the tumor from the anal verge, (neo-)adjuvant treatment, surgical procedure performed, stoma characteristics, postoperative complications, tumor classification and follow-up data on recurrence (local/regional) and metastasis.

### *Measures*

General HRQL was assessed with the validated Dutch version of the Short Form-36 (SF-36) questionnaire.<sup>11</sup> The eight subscales include physical functioning (assesses limitations to daily activities such as climbing stairs or lifting groceries), role limitations due to physical health (assesses limitations in work/activities due to physical health), bodily pain, general health perceptions, vitality (assesses energy and fatigue), social functioning, role limitations due to emotional health (assesses limitations in work/activities due to mental health), and mental health (assesses anxiety and depression). All scales were linearly converted to a 0–100 scale according to standard scoring procedures, with higher scores indicating better HRQL.

Disease-specific issues were assessed with the Dutch validated European Organization for Research and Treatment of Cancer (EORTC) module Quality of Life Questionnaire – Colorectal 38 (QLQ-CR38).<sup>12</sup> The QLQ-CR38 assess both functioning and symptom burden. Functioning consists of two scales (body image and sexual functioning), two single items (future perspective and sexual enjoyment), seven symptom scales (micturition problems, defecation problems, gastrointestinal symptoms, stoma-related problems, chemotherapy side effects, male and female sexual problems) and an item on weight loss. The items are ranged on a 4-point scale ranging from 1 (not at all) to 4 (very much). All scales were linearly converted to a 0–100 scale according to standard scoring procedures.<sup>12</sup> For the functioning scales and single items, higher scores indicate better functioning; for the symptom scales and single item, higher scores indicate higher symptom burden.

Self-reported comorbidity was categorized according to an adapted Self-administered Comorbidity Questionnaire (SCQ).<sup>13</sup> The SCQ also assesses the patient's perceived severity and burden of the comorbid condition. Socioeconomic status was determined by an indicator developed by Statistics Netherlands based on individual fiscal data from the year 2000 on the economic value of the home and household income, and provided as aggregate level for each postal code (average 17 households), which were then categorized into tertiles.<sup>14</sup> Body mass index (BMI), marital status, educational level, employment status and smoking were also assessed.

Normative data from the Dutch SF-36 validation study were used to compare the mean subscale scores between the treatment groups and the norm population.<sup>11</sup>

In 2009, CentERdata a research institute at Tilburg University, was assigned to collect normative data on sexuality

via the CentERpanel.<sup>15</sup> The CentERpanel is an online household panel consisting of over 2000 households which are representative of the Dutch-speaking population in the Netherlands. For households without internet access, additional provisions were provided to assist in data collection. In total, 1613 (75%) cancer-free panel members of  $\geq 18$  years completed three items on sexuality from the EORTC-QLQ-CR38. Members were asked to what extent over the past 4 weeks were they: (1) interested in sex; (2) sexually active; and for those who were sexually active, (3) to what extent was sex enjoyable for them. These three items were scored according to standard EORTC-QLQ-CR38 procedures.<sup>12</sup> Furthermore, sociodemographic data such as age, sex, marital status, and comorbidity were collected.

### Statistical analyses

All statistical analyses were performed using SPSS (version 17.0 for windows. SPSS Inc., Chicago, IL). Differences in clinical and demographic parameters between groups were compared using chi-square or *t*-test when appropriate. If normality and homogeneity assumptions were violated, non-parametric tests were used.

Comparisons between the treatment groups (stoma vs. non-stoma) on the SF-36 and QLQ-CR38 mean scores were performed using analysis of covariance (ANCOVA). Both groups were further stratified by age at time of surgery ( $<70$  and  $\geq 70$  years). Confounding variables were determined a priori.<sup>16</sup> Variables included for adjustment were comorbidity, level of tumor from anal verge, tumor stage, post-operative complications and disease progression. The mean SF-36 scores of the patient samples were compared with an age and sex-matched Dutch normal population. For this analysis, the groups (norm, stoma and no stoma) were stratified by age ( $<70$  years and  $\geq 70$  years) at time of survey. Comparisons were made using the independent sample *t*-test. Comparisons on the sexuality items of the QLQ-CR-38 between the treatment groups and the Dutch norm population were performed using ANCOVA, adjusted for age, marital status, comorbidity, sex, sex\*group.

Statistical differences were indicated if a *p*-value  $<0.05$  and reported *p*-values were two-sided.

## Results

### Clinical and demographic data

In total, 143 patients were included in this analysis. The median follow-up was 3.4 years (0.8–11.1 years). There were no statistically significant differences in demographic characteristics between patients with a stoma ( $n = 67$ ) and without a stoma ( $n = 76$ ). Marital status and educational level not shown.

As may be expected, stoma patients were more likely to have a tumor closer to the anal verge ( $p < 0.0001$ ) and were often treated with an APR ( $p < 0.0001$ ) (Table 1).

### HRQL

After adjustment, there was no significant effect of the presence of a stoma on any of the SF-36 subscales. However, there was a significant age effect ( $p = 0.0003$ ) on physical functioning, with older patients having a worse physical function as compared to younger patients

Table 1

Clinical and demographic characteristics of CRC survivors by stoma status at time of survey.

	Stoma ( $n = 67$ )	Non-stoma ( $n = 76$ )	<i>p</i> -Value
Age at time of surgery (median $\pm$ SD)	64.7 (11.1)	64.7 (9.3)	0.9
Years since initial diagnosis (median $\pm$ SD)	36.7 (34.1)	42.8 (29.8)	0.9
	<i>n</i> (%)	<i>n</i> (%)	
Male	41 (61.2)	48 (63.2)	0.8
Distance from anal verge (median $\pm$ SD)	4.0 (2.7)	8.2 (2.0)	$<0.0001$
Type of surgery			
Abdominal perineal resection	56 (83.6)	NA	
Low anterior resection	11 (16.4)	76 (100)	$<0.0001$
Intra operative radiotherapy (IORT)	6 (9.0)	3 (3.9)	0.2
Surgical complications <sup>a</sup>			
None	37 (55.2)	54 (71.1)	
Grade I-II	20 (29.9)	13 (17.1)	
Grade IIIa	—	2 (2.6)	
Grade IIIb	10 (14.9)	7 (9.2)	0.7
Neo-adjuvant treatment			
No neoadjuvant treatment	6 (9.0)	9 (11.8)	
Short course radiotherapy (5 $\times$ 5 Gy)	50 (74.6)	59 (77.6)	
Long course radiotherapy	1 (1.5)	—	
Chemoradiation	10 (14.9)	8 (10.5)	0.2
Adjuvant chemotherapy	14 (20.9)	8 (10.5)	0.1
pTNM stage			
I	37 (55.2)	31 (40.8)	
IIA	12 (17.9)	22 (28.9)	
IIB	1 (1.5)	—	
IIIA	4 (6.0)	6 (7.9)	
IIIB	12 (17.9)	13 (17.1)	
IIIC	1 (1.5)	4 (5.3)	0.2
Local recurrence	—	1 (1.3)	0.3
Distant metastasis	3 (4.5)	9 (11.8)	0.1
Comorbidity			
None	19 (28.4)	27 (35.5)	
1	15 (22.4)	20 (26.3)	
$>1$	33 (49.3)	29 (38.2)	0.4

Some variables do not add up to 100% due to missing data.

<sup>a</sup> According to the Clavien-Dindo classification,<sup>25</sup> grade 1 = any deviation from normal postoperative course without pharmacological treatment, grade 2 = complications requiring pharmacotherapeutic intervention, grade 3a = complications needing reintervention without general anesthesia, grade 3b = complication requiring reintervention under general anesthesia of life threatening complication requiring ICU admission.

Table 2

Mean scores ( $\pm$ SD) of general and disease specific health status of rectal cancer survivors by stoma status stratified by age at time of surgery ( $<70$  and  $\geq 70$  years).

	Stoma		No stoma		Ancova*	
	$<70$ years ( $n = 44$ )	$\geq 70$ years ( $n = 23$ )	$<70$ years ( $n = 57$ )	$\geq 70$ years ( $n = 19$ )	Stoma effect	Age effect
SF-36						
General health	66.6 $\pm$ 22.0	61.2 $\pm$ 21.6	64.2 $\pm$ 22.4	54.2 $\pm$ 16.5	n.s.	n.s.
Physical function	76.2 $\pm$ 22.6	54.2 $\pm$ 27.5	78.2 $\pm$ 21.5	63.2 $\pm$ 27.3	n.s.	0.0003
Role function-physical	65.3 $\pm$ 40.3	51.8 $\pm$ 43.9	71.5 $\pm$ 43.0	62.5 $\pm$ 43.9	n.s.	n.s.
Bodily pain	77.3 $\pm$ 23.5	77.3 $\pm$ 26.2	76.4 $\pm$ 25.6	78.9 $\pm$ 24.0	n.s.	n.s.
Vitality	67.4 $\pm$ 17.5	65.0 $\pm$ 18.8	67.8 $\pm$ 21.1	64.4 $\pm$ 18.8	n.s.	n.s.
Social function	82.1 $\pm$ 17.7	82.6 $\pm$ 19.8	80.9 $\pm$ 20.5	79.9 $\pm$ 17.2	n.s.	n.s.
Role function-emotional	77.0 $\pm$ 37.9	71.9 $\pm$ 37.3	82.3 $\pm$ 32.7	88.9 $\pm$ 19.8	n.s.	n.s.
Mental health	78.3 $\pm$ 14.1	79.8 $\pm$ 14.7	76.8 $\pm$ 18.0	74.0 $\pm$ 15.9	n.s.	n.s.
EORTC-QLQ-CR38 <sup>a</sup>						
Body image	68.2 $\pm$ 29.0	67.6 $\pm$ 29.9	76.4 $\pm$ 25.7	84.7 $\pm$ 14.5	n.s.	n.s.
Future perspective	65.1 $\pm$ 21.5	73.9 $\pm$ 28.3	70.9 $\pm$ 25.7	70.8 $\pm$ 23.9	n.s.	n.s.
Sexual function	25.2 $\pm$ 23.6	17.5 $\pm$ 21.8	24.5 $\pm$ 24.1	12.2 $\pm$ 16.0	0.009	0.005
Sexual enjoyment <sup>b</sup>	57.3 $\pm$ 24.7	23.8 $\pm$ 25.2	50.0 $\pm$ 35.7	33.3	NA	n.s.
Micturition problems	28.2 $\pm$ 21.7	29.0 $\pm$ 16.7	26.2 $\pm$ 17.4	33.3 $\pm$ 19.0	n.s.	n.s.
Chemo	10.1 $\pm$ 12.4	9.7 $\pm$ 14.7	12.5 $\pm$ 16.0	13.3 $\pm$ 13.4	n.s.	n.s.
Gastrointestinal problems	19.0 $\pm$ 15.6	18.4 $\pm$ 13.1	25.2 $\pm$ 16.1	20.8 $\pm$ 11.6	n.s.	n.s.
Male sexual dysfunction <sup>c</sup>	57.6 $\pm$ 37.0	80.5 $\pm$ 26.4	48.5 $\pm$ 34.9	66.7 $\pm$ 39.1	n.s.	0.03
Female sexual dysfunction <sup>d</sup>	44.4 $\pm$ 30.0	—	24.3 $\pm$ 33.1	—	—	—
Defecation problems	—	—	25.6 $\pm$ 16.8	28.2 $\pm$ 13.0	NA	n.s.
Stoma-related problems	26.7 $\pm$ 17.8	27.0 $\pm$ 26.7	—	—	NA	n.s.
Weight loss	3.9 $\pm$ 10.8	4.5 $\pm$ 15.6	9.1 $\pm$ 19.7	6.2 $\pm$ 18.0	n.s.	n.s.

Abbreviations: SF-36 = Short Form 36 Questionnaire; EORTC-QLQ-CR38 = European Organization for Research and Treatment of Cancer (EORTC) module Quality of life Questionnaire –Colorectal 38; n.s. = not significant; NA = not applicable; blank indicates that no statistical analyses could be performed due to missing data.

\**p*-values were adjusted for confounding variables: level tumor from anal verge (continuous variable), comorbidity, tumor stage (I = T1,T2 without lymph node positivity or metastasis; II = T3-T4 without lymph node positivity or metastasis; III any T with lymph node positivity) post-operative complications and disease progression.

<sup>a</sup> EORTC-QLQ-CR38: Body image, future perspective, sexual function and sexual enjoyment scales: higher scores indicate better function; for the other symptom scales: higher scores indicates higher symptom burden.

<sup>b</sup> Only one patient  $\geq 70$  with no stoma completed the sexual enjoyment item.

<sup>c</sup> Due to small numbers per cell, only age at treatment and stoma status were included in the model.

<sup>d</sup> No female  $\geq 70$  years provided information about female sexual dysfunction.

regardless of the presence of a stoma (54.2  $\pm$  27.5 and 63.2  $\pm$  27.3 vs. 76.2  $\pm$  22.6 and 78.2  $\pm$  21.5, respectively) (Table 2).

Comparing the HRQL scores between the 4 groups on the QLQ-CR38 domains revealed significant differences in sexual functioning and male sexual dysfunction. There was a significant age effect with older patients having worse sexual function compared to younger patients ( $p = 0.005$ ). Interestingly, older patients with a stoma had better sexual function as compared to patients without a stoma ( $p = 0.009$ ). In younger patients, sexual functioning was not influenced by the presence of a stoma. Male sexual dysfunction was significantly worse for older patients ( $p = 0.03$ ) but again this was not affected by the presence of a stoma.

No significant interaction (stoma status  $\times$  age) effect on any of the SF-36 and QLQ-C38 items was revealed.

#### HRQL compared with normative population

The SF-36 subscale scores from the 2 groups (stoma vs. no stoma) were compared with a Dutch normative population,

stratified by age at time of survey (Figs. 1 and 2). Among the  $<70$  years respondents, no significant difference was found in any of the items of the SF-36 (Fig. 1). Respondents aged  $\geq 70$  years with a stoma had a significant worse physical function as compared to the normative population (59.5 vs. 74.7  $p < 0.01$ ) but a slightly better mental health (80.8 vs. 75.6  $p < 0.05$ ) (Fig. 2). Older patients without a stoma scored better for emotional role function in comparison with the normative population (91 vs. 78.1  $p < 0.01$ ). Other items of the SF-36 showed no differences with the normative population.

#### Sexual functioning compared with normative population

On the sexuality items of the QLQ-CR38, after adjustment for several variables, sexual functioning was significantly better in the normative population as compared to younger rectal cancer patients both with and without a stoma (44.6 vs. 26.7 and 25.5, respectively,  $p < 0.0001$ ). Similar differences were revealed on sexual enjoyment (73.4 vs. 55.5 and 54.5, respectively,  $p < 0.0001$ ) (Fig. 1).



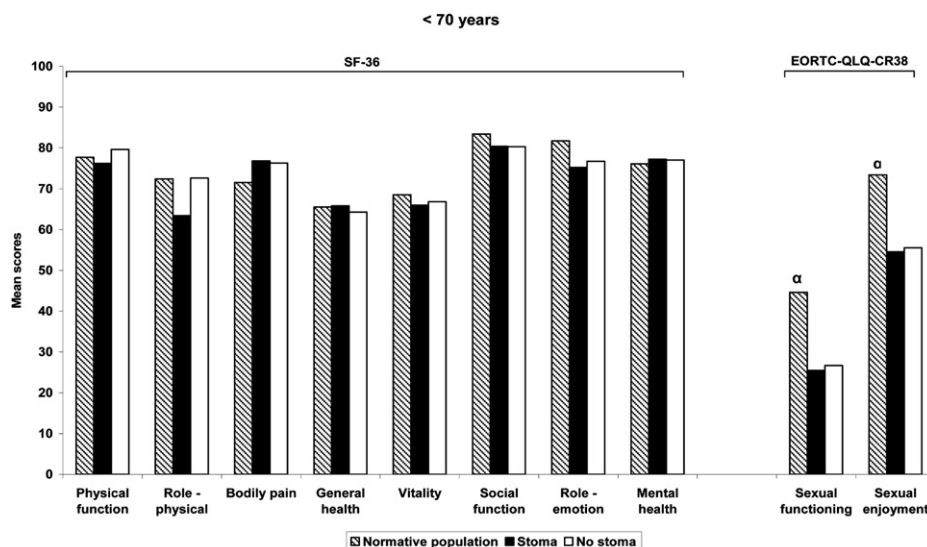


Figure 1. Mean SF-36 and EORTC-QLQ-CR38 (sexual function and sexual enjoyment) subscale scores of patients <70 years at time of survey are shown according to stoma status in comparison with an age matched Dutch normal population.

Older patients scored slightly poorer on sexual function and sexual enjoyment as compared to the normative population although these differences were not statistically significant (Fig. 2).

## Discussion

The decision between a LAR with colo-anal anastomosis and LAR/APR with a permanent stoma in a patient with a distal rectal tumor may be difficult. This is especially true for elderly patients where the assumed benefits of the avoidance of a stoma should be outweighed against the potentially life threatening postoperative complications such as anastomotic leakage. When anastomotic leakage occurs in the elderly, the ensuing mortality rate could be up to

57% in the first 6 months post-operation. Furthermore, other post-operative complications such as abscesses, sepsis and cardiac and pulmonary problems have also been related to a significant increased mortality rate in elderly compared to younger patients.<sup>17</sup>

### *Influence of a stoma on HRQL*

In the current study it was revealed that the presence of a stoma had only a minor influence on the HRQL, irrespective of age. Age itself seemed to be of more impact since older patients experienced worse physical functioning as compared to younger patients irrespective of the presence of a stoma. These findings are in accordance with recently published data, showing that the HRQL levels of older patients do not

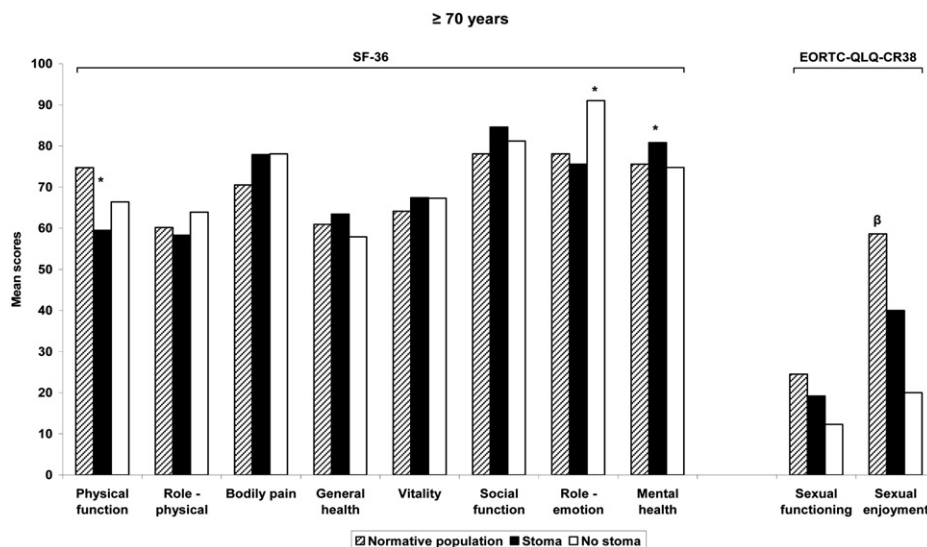


Figure 2. Mean SF-36 and EORTC-QLQ-CR38 (sexual function and sexual enjoyment) subscale scores of patients ≥70 years at time of survey are shown according to stoma status in comparison with an age matched Dutch normal population.

reach baseline levels even after 2 years post-surgery, which suggests that the elderly will suffer a more permanent impaired physical function after surgery for rectal cancer.<sup>7</sup>

In the QLQ-CR38 sexuality domains, age was related to more dysfunction, irrespective of the presence of a stoma. Interestingly, older patients with a stoma scored significantly better on the sexuality subscales than those without a stoma.

#### *HRQL of rectal cancer patients after treatment*

In order to relate the HRQL of rectal cancer patients after treatment, a comparison was made to a Dutch normative population. This revealed that younger patients have a similar general HRQL as compared to the normative population. Older patients with a stoma had a significant lower physical function but better mental health compared to the normative population. Moreover, older patients without a stoma had a higher emotional role function compared to the normative population. Altogether, HRQL in rectal cancer patients is almost similar to that of a normative population in spite of the extensive treatment that these patients often have undergone. This finding may be somewhat counter intuitive at first but was also demonstrated in other recent studies.<sup>18,19</sup> This phenomenon is now referred to as “response shift”, whereby patients change their internal standards as an adaptation to limitations caused by the disease or its treatment.<sup>20</sup>

#### *Sexual dysfunction following treatment*

In this study the prevalence of sexual dysfunction following treatment is high, particularly when compared to the normative population. Sexual problems are well-known after rectal cancer as recently reviewed, with an incidence of dysfunction of 23–69% in men and 30–40% of previously sexually active patients reporting inactivity following treatment.<sup>21</sup> Given the high incidence of sexual problems and the impact on the HRQL, this should be part of information provision prior to surgery. Furthermore this problem should be addressed and treated whenever possible in rectal cancer survivors by providing psychosocial and clinical support.

All together, the current study shows that the impact of a stoma on the HRQL of rectal cancer patients is small regardless of age. Similar findings were recently reported in a large meta-analysis and Cochrane review. In addition, other recent studies showed that other specific parameters, such as gender and post-operative complications, have more impact on the quality of life than having a stoma.<sup>22–24</sup> We believe that a permanent stoma is feasible for elderly and frail patients with a low situated rectal tumor, particularly when the patient is at ‘high’ risk for post-operative complications due to co-morbidities or frail condition.

The strengths of the present study include the availability of clinical data, the usage of a population based sample

data, availability of a validated questionnaire for comparison with Dutch normative population and relatively long-term follow-up of up to 11 years.

### **Conclusion**

This study shows comparable HRQOL of older patients with a stoma to older patients without a stoma or the normative population. Keeping in mind the severe impact that post-operative complications, in particular anastomotic leakage, can have on clinical recovery, a permanent stoma is feasible for elderly patients with a low situated rectal carcinoma. The negative impact of treatment on sexual functioning as found in the current study calls for further attention to alleviate this problem in sexually active patients.

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### **Conflict of interest statement**

None declared.

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